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Washington, D.C. 20231

Paul Grandinetti  
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1725 K Street, N.W. Suite 1401  
Washington, D.C. 20006-1401

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,976,273

### DENIAL OF PATENT TERM EXTENSION

An application for patent term extension of U.S. Patent No. 4,976,273, issued December 11, 1990, based upon the product REALITY Female Condom was filed on July 2, 1993. An application also based upon the product REALITY Female Condom of U.S. Patent No. 4,735,621 was also filed by applicant.

On August 4, 1995, a Notice of Final Determination was mailed both applications for patent term extension informing applicant that both patents qualified for patent term extension<sup>1</sup> but for the fact that the term of only one patent may be extended for the same regulatory review period for a product. 35 U.S.C. § 156(c)(4). Applicant was given a period of one month to elect the patent for which patent term extension was desired.

On September 5, 1995, applicant filed a paper electing to have the term of U.S. Patent No. 4,735,621 extended under the statute. Accordingly, the application for extension of the term of U.S. Patent No. 4,976,273 is denied.

Jeffrey Nase  
Patent Legal Administrator  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: REALITY  
FDA Docket No.: 93E-0268

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<sup>1</sup>The Notice of Final Determination was based upon an extension being added to the 17-year term. Since the extension is added to the 20-year term, the Notice of Final Determination was in error. See Merck & Co. v. Kessler, 38 USPQ2d 1347 (CAFC 1996). Both patents have a twenty year term that expires after the fourteen year limit of 35 U.S.C. § 156(c)(3). Accordingly, neither patent is eligible for patent term extension.